



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,745	07/10/2006	Takuya Hayashi	40154	8189

116 7590 12/05/2007
PEARNE & GORDON LLP
1801 EAST 9TH STREET
SUITE 1200
CLEVELAND, OH 44114-3108

EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
----------	--------------

1623

MAIL DATE	DELIVERY MODE
-----------	---------------

12/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,745	Applicant(s) HAYASHI ET AL.	
	Examiner Everett White	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 16-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/4/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8 and 11-15, drawn to a composition comprising a chitosan derivative that contains carbohydrate chains, classified in class 536, subclass 20.
- II. Claims 9 and 10, drawn to an endoscopic system comprising a device for injecting a composition, classified in class 600, subclass 101 plus.
- III. Claims 16-23, drawn to a method of conducting endoscopic surgery, classified in class 606, subclass 46.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process such as implants or binding of corporeal tissue, sealing of liquids and gases, prevention of adhesion, against embolisms, skin care and hair protection.

Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practice by hand.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, because the inventions require a different field of search (see MPEP § 808.02), and because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Serbinowski on October 31, 2007 a provisional election was made with traverse to prosecute the invention of III, claims 16-23.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Potential Rejoinder of Process Claims in Ochiai/Brouwer Situation

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onuki et al (US Patent No. 7,063, 715 B2) in view of Hirofumi et al (WO 00/27889, also see English Language equivalent US Pat. No. 6,806,260) or Sung et al (US Patent No. 6,624,138). Applicants claim a method of conducting endoscopic surgery comprising: targeting mucous membrane of a patient that is in need of bulging during endoscopic surgery; administering to said targeted mucous membrane a composition comprising a chitosan derivative containing

carbohydrate chains; and bulging said targeted mucous membrane as a result of administration of said composition.

The Onuki et al patent discloses an endoscopic suture apparatus that can be endoscopically inserted into a living body cavity and can suture or ligate organic tissues. More particularly, the invention relates to an endoscopic suture apparatus for performing suture to treat a damaged part of the tissue of the digestive canal or to reliably arrest hemorrhage in a bleeding region and to form an artificial valve in the treatment of a gastro-esophageal reflux disease (see column 1, 2nd paragraph). See column 14, last paragraph of the Onuki et al patent wherein a description of using the endoscope is disclosed which involve the endoscope being inserted into a target region, and the injection needle of the endoscope is projected from the distal end of the endoscope whereby a physiological saline or other solution is injected under a mucous membrane of an organ by means of the needle. In this paragraph, Onuki et al discloses that the higher the viscosity of the solution, the longer the bulging time of the mucous membrane.

The instantly claimed method of conducting endoscopic surgery differs from the method of the Onuki et al patent by claiming administration of a composition comprising a chitosan derivative containing carbohydrate chains.

The Hirofumi et al WO publication discloses a functional chitosan derivative which comprises a chitosan, which is a natural polysaccharide, and incorporated therein at least one of a saccharide, a photoreactive functional group, an amphipathic group, and a glycosaminoglycan (see abstract), which embraces the chitosan derivative described in instant Claims 16 and 18-21. See column 22, 3rd paragraph of the Hirofumi et al publication wherein functional chitosan derivative can self-crosslinked by photo-irradiation due to incorporation of the photoreactive functional groups, which embraces the subject matter of instant Claim 22. In the English Language equivalent (US Pat. 6,606,260), Hirofumi et al discloses using the functional chitosan derivative in the medical field as wound dressings, antiadhesive materials, hemostatics, and sealants for body fluids or gases. The description of the use of the functional chitosan derivative as sealants for body fluids or gases falls within the scope of sutures.

The Sung et al patent is cited to show that it is known that chitosan compounds can be delivered to the body using an endoscopic instrument (see column 8, lines 58 and 63 and 64).

One of ordinary skill in this art would be motivated to combine the teaching of the Onuki et al patent with the Hirofumi et al WO publication and the Sung et al patent since each of the documents suggests the use of chitosan compounds for medical applications.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute solution administered by the endoscopic suture apparatus of the Onuki et al patent with a composition comprising a functional chitosan derivative in view of the recognition in the art, as evidenced by the Hirofumi et al publication and the Sung et al patent, that chitosan compounds administered via an endoscopic instrument are effective as sealants for body fluids or gases and other medical applications.

Summary

Claims 16-23 are rejected; Claims 1-15 are withdrawn from consideration as being drawn to non-elected inventions.

Examiner's Telephone Number, Fax Number, and Other Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APPLICATION/CONTROL NUMBER:
10/576,745
ART UNIT: 1623

PAGE 7

E. White


Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600